1 of 2

K070975

JUN 21 2007

510(k) SUMMARY

Submitter

Keith Dunn
Hu-Friedy Mfg. Co., Inc.
3232 N. Rockwell St.
Chicago, IL 60618
Tel. 773-975-6100 Fax 773-868-3558

Date Prepared 03/30/07

Device Name

Trade name	Symmetry IQ
Common name	Dental Ultrasonic Scaler
Classification name	Ultrasonic Scaler

Legally marketed Devices to which equivalence is claimed:

Nakanishi, Inc. Varios 150/350/550	K031421

Description of the device
The Hu-Friedy® brand Symmetry IQ Ultrasonic Scalers are similar to the Ultrasonic Scalers of the predicate device listed above.

These devices are intended for use by dental professionals only. These devices generate ultrasonic vibrations intended for use in dental applications such as scaling, periodontal therapy, root canal treatment and cavity preparation.

Hu-Friedy will purchase the generators from NSK, Inc. (Nakanishi) and own brand private label the device. The modifications to the Hu-Friedy product are cosmetic in nature and consist mainly of new shape and design to the housing of the control unit. All of the internal electrical and technical specifications are identical to the marketed NSK units. Hu-

Friedy currently has a 510k (K053178) approval for the Symmetry line of piezoelectric tips that are compatible with Satelec and NSK piezoelectric ultrasonic scalers. The addition of the Symmetry IQ generators and handpiece will complete our ultrasonic piezo scaling product line.

The Symmetry IQ Ultrasonic Scalers have essentially the same design as the predicate device's ultrasonic generators. The Symmetry IQ 2000 series is equivalent to the Varios 150 Lux (Optic), which is an integrated version of the Varios 350 Lux (Optic) to be used in the delivery tray table as a built in system. The Symmetry IQ 3000 series is equivalent to the combination of the Varios 550 control unit with the handpiece used in the Varios 350 Lux (Optic). The Symmetry IQ 3000 unit is based on the NSK Varios 560 which is currently pending FDA 510k approval. The addition of a silicone grip to the ultrasonic generator handpiece used in both models is the only significant change and the reason for the new 510k application. Hu-Friedy performed laboratory tests such as a sterilization study of the handpiece (study #582), biocompatibility testing of the silicone grip(study #574) and ISO 22374 life testing(study#579) of the ultrasonic unit to determine the safety of the Symmetry IQ generators and handpiece.

The decision to private label NSK ultrasonic generators was made after market research and a focus group study(study #581) were conducted by Hu-Friedy. The key features of the Varios line of NSK scalers such as fiber-optic lighted handpieces, easy to read touchpad controls, quick connect components and broad range of power settings met the Hu-Friedy customer requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Keith Dunn
Director Regulatory Affairs & Quality Systems
Hu-Friedy Manufacturing Company, Incorporated
3232 North Rockwell Street
Chicago, Illinois 60618

JUN 21 2007

Re: K070975
Trade/Device Name: Symmetry IQ Ultrasonic Generator
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: March 30, 2007
Received: April 6, 2007

Dear Mr. Dunn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070975

Indications for Use

510(k) Number (if known): _____

Device Name: Symmetry IQ Ultrasonic Generator

Indications for Use:
This product is intended for use by dental professionals only. This device generates ultrasonic vibrations intended for use in dental applications such as scaling, periodontal therapy, root canal treatment and cavity preparation.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K070975

Section 4-1